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Attorney Docket No.: 050623.00211

**Amendment to the Specification:**

The following amendments to the specification refer to the page and line numbers in the specification as filed on July 15, 2003.

Please replace the paragraph beginning on page 5, line 9 with the sentence, "It is known in the art, that the  $T_g$  of a polymer may depend on a method of measuring the  $T_g$ ," with the following amended paragraph:

It is known in the art[[,]] that the  $T_g$  of a polymer may depend on a method of measuring the  $T_g$ . For the purposes of the present invention, the  $T_g$  for all polymers discussed below have been determined using the method of differential scanning calorimetry (DSC). DSC measures the change in heat capacity of a semicrystalline polymer as the polymer is exposed to an increasing temperature. Also, it has to be kept in mind that some hydrophilic polymers having a relatively high  $T_g$  (e.g., about 50°C or higher) when in a dry state, may have significantly lower  $T_g$  in the aqueous environment such as inside the patient's body. This phenomenon may be caused by the fact that when the hydrophilic polymer is placed in contact with the body fluids (e.g., blood), the polymer can absorb water which serves as plasticizer leading to substantial reduction of the polymer's  $T_g$ . The term "dry state" is defined as a condition of a polymer when the polymer contains less than about 1 mass % of water at equilibrium, at ambient conditions. To illustrate, polymers capable of absorbing at least 1% of water (as a percentage of the polymer's weight), at room temperature and ambient pressure, can have their  $T_g$  substantially ~~lower~~ lowered when the polymer is exposed to the aqueous environment than when the polymer is dry. For example, the  $T_g$  of dry poly(ethylene-co-vinyl alcohol)(also known as EVAL™ EVAL) is about 55°C (328°K), and the  $T_g$  of poly(D,L-lactide) is about 50°C (323°K). However, EVAL is capable of absorbing maximum about 5% of water, and poly(D,L-lactide) is capable of

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absorbing maximum about 1% of water at ambient temperature and pressure. The  $T_g$  of both EVAL and poly(D,L-lactide) which absorbed the maximum amount of water they are capable of absorbing is within the range of between about 35°C (308°K) and about 42°C (315°K) range. Thus, the  $T_g$  of such and similar hydrophilic polymers can be lower by as much as 20 degrees after the polymer has absorbed the maximum amount of water.

Please replace the paragraph beginning on page 6, line 8 with the phrase, "According to one embodiment of the present invention, the drug-polymer layer . . .," with the following amended paragraph:

According to one embodiment of the present invention, the drug-polymer layer or the topcoat layer of the stent coating can be fabricated of a homopolymer, a copolymer or a terpolymer ~~having~~ that can have the preferred  $T_g$  in a dry state (1) between about 20°C (293°K) and about 55°C (328°K); (2) between about 35°C (308°K) and about 50°C (323°K); (3) between about 37°C (310°K) and about 50°C (323°K); (4) between about 37°C (310°K) and about 40°C (313°K); or (5) about 37°C (310°K).

Please replace the paragraph beginning on page 6, line 14 with the phrase, "According to another embodiment of the present invention, the  $T_g$  of the polymer . . .," with the following amended paragraph:

According to another embodiment of the present invention, the  $T_g$  of the polymer forming the topcoat layer is greater than, or equal to, the  $T_g$  of the polymer forming the drug-polymer layer. Yet in another embodiment, the  $T_g$  of the polymer forming the topcoat layer can be less than the  $T_g$  of the polymer forming the drug-polymer layer. In yet another embodiment, the  $T_g$

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of the polymer forming at least one of the drug-polymer and the topcoat layers is within the preferred ranges described above, while the  $T_g$  of the polymer forming the other layer is outside the ranges. For example, the topcoat layer can be formed of a polymer having ~~the~~  $T_g$  within any of the previously described ranges (e.g., 37-40°C), while the polymer forming the drug-polymer layer can have ~~the~~  $T_g$  above 50°C, e.g., 55°C. Yet in another example, the drug-polymer layer can be formed of a polymer having ~~the~~  $T_g$  within any of the previously described ranges (e.g., 37-40°C), while the polymer forming the topcoat layer can have ~~the~~  $T_g$  above 50°C, e.g., 55°C.

Please replace the paragraph beginning on page 7, line 3 with the phrase, "For polymers forming, for example, a topcoat layer and having a  $T_g$  of at least 35-37°C, . . .," with the following amended paragraph:

For polymers forming, for example, a topcoat layer and having a  $T_g$  of at least 35-37°C, when the temperature of the patient increases above normal body temperature and reaches at least the  $T_g$  of the polymer, the morphology of the polymer changes to a more rubbery consistence; consistency, which allows for an increased rate of release of the drug. When the temperature of the patient falls below the polymer's  $T_g$ , the polymer becomes hard again which results in the reduction of the rate of release of the drug.

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Please replace the paragraph beginning on page 15, line 4 with the phrase, "Representative examples of some solvents include N,N-dimethylacetamide (DMAC), . . .," with the following amended paragraph:

Representative examples of some solvents include N,N-dimethylacetamide (DMAC), N,N-dimethylformamide (DMF), tetrahydrofuran (THF), cyclohexanone, xylene, toluene, acetone, methyl ethyl ketone, propylene glycol monomethyl ether, methyl butyl ketone, ethyl acetate, *n*-butyl acetate, and dioxane. Examples of mixtures of solvents include mixtures of DMAC and methanol (e.g., a 50:50 by mass mixture), cyclohexanone and acetone (e.g., 80:20, 50:50, 20:80 by mass mixtures), acetone and xylene (e.g. a 50:50 by mass mixture), and acetone, ~~FLUX REMOVER AMS~~, FLUX REMOVER AMS™, and xylene (e.g., a 10:50:40 by mass mixture). FLUX REMOVER AMS is the trade name of a solvent manufactured by Tech Spray, Inc. of Amarillo, Texas comprising about 93.7% of a mixture of 3,3-dichloro-1,1,1,2,2-pentafluoropropane and 1,3-dichloro-1,1,2,2,3-pentafluoropropane, and the balance methanol, with trace amounts of nitromethane.

Please replace the paragraph beginning on page 17, line 14 with the phrase, "Examples of drugs include antiproliferative substances such as actinomycin D, or . . .," with the following amended paragraph:

Examples of drugs include antiproliferative substances such as actinomycin D, or derivatives and analogs thereof (manufactured by Sigma-Aldrich of Milwaukee, Wisconsin, or COSMEGEN available from Merck). Synonyms of actinomycin D include dactinomycin, actinomycin IV, actinomycin I<sub>1</sub>, actinomycin X<sub>1</sub>, and actinomycin C<sub>1</sub>. The active agent can also

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fall under the genus of antineoplastic, anti-inflammatory, antiplatelet, anticoagulant, antifibrin, antithrombin, antimitotic, antibiotic, antiallergic and antioxidant substances. Examples of such antineoplastics and/or antimitotics include paclitaxel (e.g. TAXOL<sup>®</sup> by Bristol-Myers Squibb Co., Stamford, Conn.), docetaxel (e.g. Taxotere<sup>®</sup> TAXOTERE<sup>®</sup>, from Aventis S.A., Frankfurt, Germany) methotrexate, azathioprine, vincristine, vinblastine, fluorouracil, doxorubicin hydrochloride (e.g. ~~Adriamycin<sup>®</sup>~~ ADRIAMYCIN<sup>®</sup> from Pharmacia & Upjohn, Peapack N.J.), and mitomycin (e.g. ~~Mutamyoin<sup>®</sup>~~ MUTAMYCIN<sup>®</sup> from Bristol-Myers Squibb Co., Stamford, Conn.). Examples of such antiplatelets, anticoagulants, antifibrin, and antithrombins include sodium heparin, low molecular weight heparins, heparinoids, hirudin, argatroban, forskolin, vapirost, prostacyclin and prostacyclin analogues, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antagonist antibody, recombinant hirudin, and thrombin inhibitors such as ANGIOMAX<sup>™</sup> Angiomax<sup>™</sup> (Biogen, Inc., Cambridge, Mass.). Examples of such cytostatic or antiproliferative agents include angiopeptin, angiotensin converting enzyme inhibitors such as captopril (e.g. CAPOTEN<sup>®</sup> ~~Capoten<sup>®</sup>~~ and CAPOZIDE<sup>®</sup> ~~Capozide<sup>®</sup>~~ from Bristol-Myers Squibb Co., Stamford, Conn.), cilazapril or lisinopril (e.g. PRINIVIL<sup>®</sup> ~~Prinivil<sup>®</sup>~~ and PRINZIDE<sup>®</sup> ~~Prinzide<sup>®</sup>~~ from Merck & Co., Inc., Whitehouse Station, NJ); calcium channel blockers (such as nifedipine), colchicine, fibroblast growth factor (FGF) antagonists, fish oil (omega 3-fatty acid), histamine antagonists, lovastatin (an inhibitor of HMG-CoA reductase, a cholesterol lowering drug, brand name MEVACOR<sup>®</sup> ~~Mevacor<sup>®</sup>~~ from Merck & Co., Inc., Whitehouse Station, NJ), monoclonal antibodies (such as those specific for Platelet-Derived Growth Factor (PDGF) receptors), nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitors, suramin, serotonin blockers, steroids, thioprotease inhibitors, triazolopyrimidine (a PDGF antagonist), and nitric oxide. An

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example of an antiallergic agent is permirolast potassium. Other therapeutic substances or agents which may be appropriate include alpha-interferon, genetically engineered epithelial cells, tacrolimus, dexamethasone, and rapamycin and structural derivatives or functional analogs thereof, such as 40-O-(2-hydroxy)ethyl-rapamycin (known by the trade name of everolimus ~~EVEROLIMUS~~ available from Novartis), 40-O-(3-hydroxy)propyl-rapamycin, 40-O-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, and 40-O-tetrazole-rapamycin.

Please replace the paragraph beginning on page 19, line 4 immediately following the heading "Example 1" and beginning with the phrase, "A polymer solution containing between about 0.1 mass % and about 15 mass %, . . .," with the following amended paragraph:

A polymer solution containing between about 0.1 mass % and about 15 mass %, for example, about 2.0 mass % of EVAL and the balance, DMAC solvent, can be prepared. The solution can be applied onto a stent to form a primer layer. To apply the primer layer, a spray apparatus, such as an EFD 780S™ ~~EFD 780S~~ spray nozzle with a ~~VALVEMATE 7040~~ VALVEMATE 7040™ control system, manufactured by EFD, Inc. of East Providence, Rhode Island can be used. The EFD 780S spray nozzle is an air-assisted external mixing atomizer. The composition is atomized by air and applied to the stent surfaces. During the process of applying the composition, the stent can be optionally rotated about its longitudinal axis, at a speed of 50 to about 150 rpm. The stent can also be linearly moved along the same axis during the application.

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Please replace the paragraph beginning on page 19, line 13 with the phrase, "The EVAL solution can be applied to a 13-mm TETRA stent (available from Guidant Corporation) . . . ," with the following amended paragraph:

The EVAL solution can be applied to a 13-mm ~~TETRA~~ TETRA™ stent (available from Guidant Corporation) in a series of 10-second passes, to deposit, for example, 10 µg of coating per spray pass. Instead of the 13-mm TETRA stent, another suitable stent can be used, for example, a 12-mm ~~VISION~~ VISION™ stent (also available from Guidant Corporation). Between the spray passes, the stent can be dried for about 10 seconds using flowing air with a temperature of about 60°C. Five spray passes can be applied, followed by baking the primer layer at about 140°C for about 2 hours. As a result, a primer layer can be formed having a solids content of about 50 µg. "Solids" means the amount of the dry residue deposited on the stent after all volatile organic compounds (e.g., the solvent) have been removed.

Please replace the paragraph beginning on page 20, line 3 with the phrase, "(b) between about 0.1 mass % and about 2 mass %, for example, . . . ," with the following amended paragraph:

(b) between about 0.1 mass % and about 2 mass %, for example, about 1.0 mass % of an active agent, for example, everolimus ~~EVEROLIMUS~~; and